MEDICAL DEVICE SINGLE AUDIT PROGRAM IN JAPAN

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MDSAP Pilot

- The MDSAP Pilot is intended to allow MDSAP recognized Auditing Organizations to conduct a single audit of a medical device manufacturer.
- A Single Audit will satisfy the relevant requirements of the medical device regulatory authorities participating in the pilot program.
- Japan announced it’s participation to MDSAP Pilot in June 2015.
- PMDA has participated in assessments as assessors since the announcement.
- MHLW and PMDA issued the guidance about the trial acceptance of MDSAP audit reports in June 2016.

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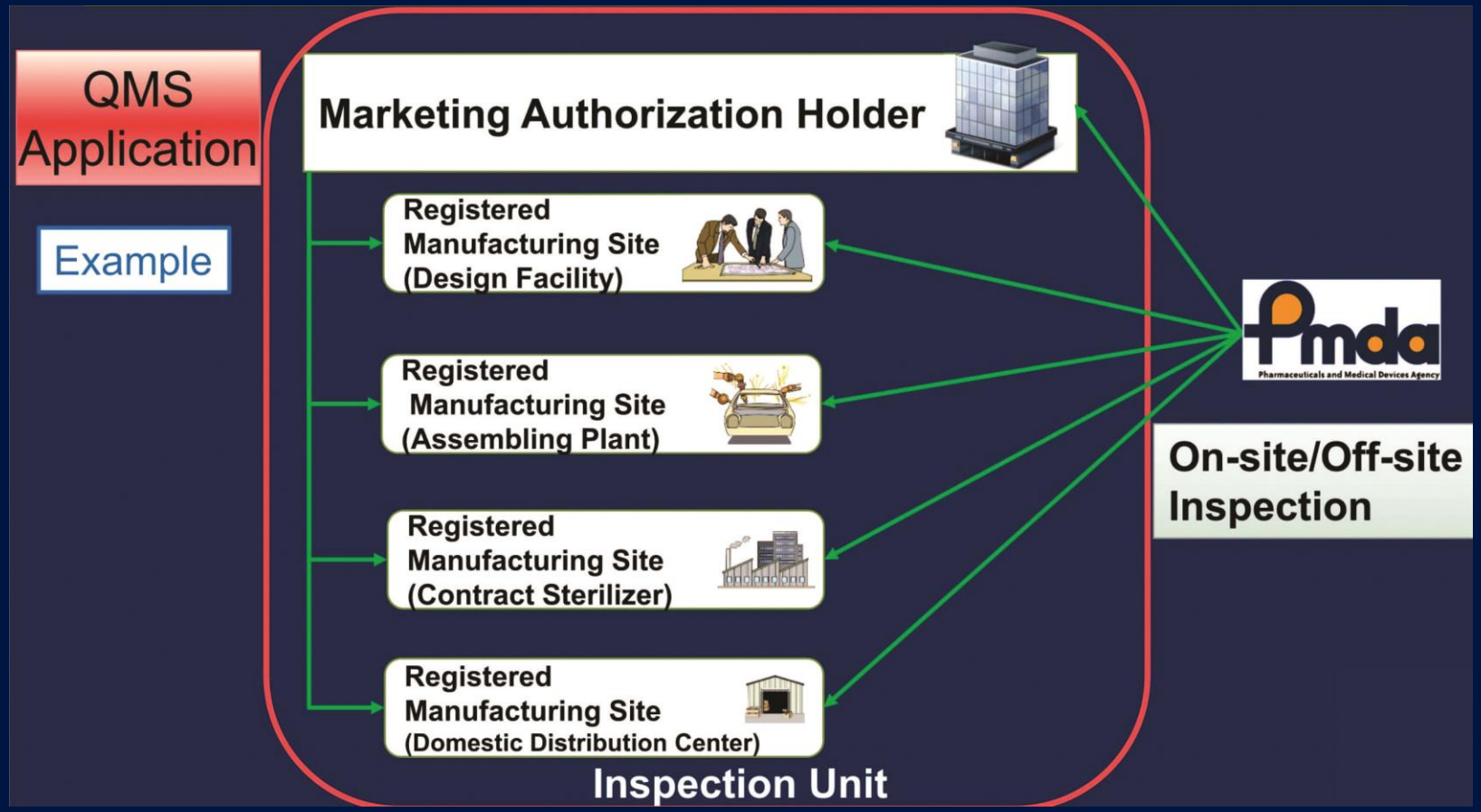
Outline of QMS inspection in JAPAN



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TRIAL acceptance of MDSAP Audit REPORTS

- PMDA is accepting MDSAP audit reports on a trial basis.
- The trial period: June 22, 2016 to December 31, 2016
- The MDSAP can reduce the manufacturer’s burden in the inspection process.
- PMDA will perform the MDSAP trial without any additional fee.
- The training materials to audit including Japan’s regulatory requirements were provided to the Auditing Organizations (AOs) in November 2015.

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ACCEPTABLE MDSAP AUDIT REPORTS FOR TRIAL

- The most recent INITIAL or RECERTIFICATION MDSAP Audit Reports

Or

- Surveillance MDSAP Audit Report with the most recent INITIAL or RECERTIFICATION CMDCAS (Canada) Audit Report issued by the same MDSAP AO (Auditing Organization).
  - In this case, PMDA will decide whether it can accept the report on a case-by-case basis.

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General rule for acceptance to the MDSAP trial program

- PMDA basically performs Off-Site Inspection for a site for which a MDSAP Audit report is submitted, at the time of QMS Inspection Application.
- Exceptions:
  - A Registered Manufacturing Site (RMS) which manufactures medical devices made of human/animal tissues
  - A RMS which manufactures radioactive IVDs, and
  - A Designated-Marketing Authorization Holder (MAH)
- PMDA can perform On-site Inspection, when necessary.

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MDSAP Process

Audit conducted by AO for RMS

Audit Report submitted to PMDA for QMS application

PMDA accepts the Audit Report under the MDSAP Trial Program

Transition of On-Site inspection to Off- Site inspection*

Reduction of the documents necessary to be submitted for Off-Site inspection.

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Required documents for an off-site inspection with MDSAP

No.	Documents	Normal Application	Application using MDSAP
1.	Arrangement of the facility	Yes	No
2.	Floor Plan	Yes	No
3.	Organization Chart	Yes	No
4.	Quality Manual	Yes	No
5.	List of Documents used in QMS	Yes	No
6.	Summary of Medical Device File	Yes	Yes
7.	State of implementation of validation	Yes	No
8.	Any documentation which indicates the confirmation result of quality of a medical device to ensure safety of it, when the device is using biologically derived raw materials etc.	Yes	Yes
9.	Procedure etc., for communication with MAH in relation to adverse events	Yes	No
10.	Agreement with Registered Manufacturing Site	Yes	No

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Notes

- PMDA may request additional documents
- Examples
  - If, at the time of the MDSAP Audit, the manufacturer did not export medical device to Japan, then PMDA may request additional documents because Japanese Specific Requirements are not audited.
  - If the MDSAP Audit Report was performed before February 2016, then the PMDA may request additional information, since the audits prior to February 2016 were not performed according to the revised model (which includes Japanese requirements).

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Conclusion

- When to submit the MDSAP Audit Reports? – Along with the QMS Inspection Application.
- The MDSAP Audit Report allows to switch to Off-site Inspection.
- The MDSAP audit reports reduces the amount of documents required for Off-site inspection.

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